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IMPROVEMENT IN THROMBOEMBOLIC OUTCOMES WITH WARFARIN IN PATIENTS WITH NON-VALVULAR ATRIAL FIBRILLATION OVER THE LAST TWO DECADES

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With the development of several new anti-thrombotic agents for stroke prevention in patients with atrial fibrillation (AF), the role of warfarin in the current era would have to be better characterized. We aimed to determine the safety and efficacy estimates reported in contemporary trials using warfarin in comparison to the prior trials.

Methods: Randomized controlled trials (RCTs) comparing warfarin to an alternative anti-thrombotic strategy for stroke prevention in AF, published between 2000 - 2011, were utilized. RCTs conducted between 1989 - 2000, listed in the prior meta-analysis (published in 1999 by Hart et al) were retrieved and served as the comparison group.

Results: There has been a reduction in the rate of thromboembolic events in the current era (1.66%/year) in comparison to the earlier trials (2.09%/year). Although there was a significant heterogeneity in the definition of the target therapeutic range in the earlier trials, the target INR range was uniformly 2.0 - 3.0 in the contemporary trials. Moreover, there was a significant improvement in the proportion of time spent in therapeutic range in the contemporary trials.

Conclusions: There has been a reduction in the thromboembolic event rate in the contemporary era, compared to the rates reported in earlier RCTs. This may be attributable to an improved anticoagulation quality in the current era. These rates should form the framework for development of future superiority and non inferiority clinical trials in this area.

Trial/Year	Patient-years	Target INR	% Time in therapeutic range	Strokes/ TIA/ non-CNS embolism	All-cause mortality	Major bleeding
PRIOR META ANALYSIS (Hart et al, 1999)						
AFASAK/ 1989	413	2.8 - 4.2	42.0	9 (2.18)	-	-
BAATAF/ 1990	487	1.5 - 2.7	83.0	2 (0.41)	11 (2.26)	3 (0.62)
SPAF/ 1991	263	2.0 - 4.5	71.0	8 (3.04)	6 (2.31)	4 (1.54)
CAFA/ 1991	237	2.0 - 3.0	43.7	8 (3.38)	-	5 (2.50)
SPINAF/ 1992	440	1.4 - 2.8	56.0	5 (1.14)	15 (3.30)	6 (1.36)
EAFT/ 1993	507	2.5 - 4.0	59.0	20 (3.95)	41 (8.09)	13 (2.56)
Pooled estimate (95% CI)	2347			2.09 (0.89 - 3.30)	3.82 (1.60 - 6.05)	-*
CURRENT META ANALYSIS						
SPORTIF III/ 2003	2440	2.0 - 3.0	66.0	56 (2.30)	79 (3.20)	41 (1.80)
SPORTIF V / 2005	3212	2.0 - 3.0	68.0	37 (1.20)	123 (3.80)	84 (3.10)
ACTIVE-W / 2006	4242	2.0 - 3.0	63.8	59 (1.40)	158 (3.76)	93 (2.21)
BAFTA/ 2007	1318	2.0 - 3.0	67.0	22 (1.68)	107 (8.00)	25 (1.89)
AMADEUS/ 2008	2159	2.0 - 3.0	63.0	27 (1.30)	61 (2.90)	29 (1.40)
RE-LY/ 2009	12044	2.0 - 3.0	64.0	199 (1.69)	487 (4.13)	397 (3.36)
ROCKET-AF/ 2011	14028	2.0 - 3.0	55.0	243 (2.20)	250 (2.21)	386 (3.40)
ARISTOTLE/ 2011	16346	2.0 - 3.0	62.2	265 (1.60)	669 (3.94)	462 (3.09)
Pooled estimate (95% CI)	55789			1.66 (1.41 - 1.91)	3.83 (3.07 - 4.58)	-*

Table 1: Characteristics, individual outcomes and pooled event rates in atrial fibrillation patients on warfarin for stroke prevention reported in prior studies in comparison to contemporary studies.

* Not pooled due to heterogeneity in definition of major bleeding across trials.